

JUL 28 2004

Special 510(k) Premarket Notification  
GE Medical Systems - Tethered Portable Digital Radiographic Detector  
July 14, 2004

12041922

**Attachment B:**  
*Summary of Safety and Effectiveness*  
*Prepared in accordance with 21 CFR Part 807.92(c).*



GE Medical Systems

General Electric Company  
P.O. Box 414, Milwaukee, WI 53201

Submitter: GE Medical Systems  
PO Box 414  
Milwaukee, WI 53201

Contact Person: D. Duersteler  
Safety and Regulatory Engineering  
Telephone: 262-312-7029; Fax: 262-312-7144

Date Prepared: July 14, 2004

Device Name: GE Tethered Portable Digital Radiographic Detector.  
Mobile X-ray System, 21 CFR 892.1720, 90 IZL

Marketed Device: GE Digital Radiographic Imaging System, 510(k) Number K982196, currently in commercial distribution.

Device Description: The GE Tethered Portable Digital Radiographic Detector is a digital X-Ray detector comprised of amorphous silicon with a cesium iodide scintillator that has been repackaged for mobile and portable use, and may be used as a film cassette replacement in portable radiography units.

Indications for Use: The GE Tethered Portable Digital Radiographic Detector is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

Comparison with Predicate Device: The GE Tethered Portable Digital Radiographic Detector is of a comparable type and substantially equivalent to the currently marketed GE Digital Radiographic Imaging System. It has the same X-ray detection technology, the same technological characteristics, the same materials, and is comparable in key safety and effectiveness features. It uses the same basic design and construction except it has been made more rugged, and the weight and power corequirements have been reduced. It has the same intended uses as the predicate device.

Summary of Studies: The device has been evaluated for electrical, mechanical, and radiation safety, and conforms with applicable medical device safety standards.

Clinical Tests: None required.

Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. Intended uses and fundamental scientific technology are the same as the legally marketed GE Digital Radiographic Imaging System. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with factory surveillance. Therefore, it is the opinion of GE Medical Systems that the GE Tethered Portable Digital Radiographic Detector is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUL 28 2004**

Mr. David Duersteler  
Safety and Regulatory Engineering  
General Electric Company  
GE Medical Systems  
P.O. Box 414  
MILWAUKEE WI 53201

Re: K041922  
Trade/Device Name: GE Tethered Portable Digital  
Radiographic Detector  
Regulation Number: 21 CFR 892.1720  
Regulation Name: Mobile x-ray system  
Regulatory Class: II  
Product Code: 90 IZL  
Dated: July 14, 2004  
Received: July 16, 2004

Dear Mr. Duersteler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

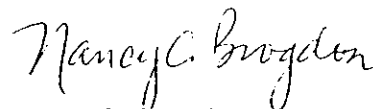
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K041922

Device Name: GE Tethered Portable Digital Radiographic Detector

Indications for Use

The GE Tethered Portable Digital Radiographic Detector is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801-109)

OR Over-The-Counter Use \_\_\_\_\_

David A. Syman  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K041922